REMARKS

Reconsideration of the present application is hereby requested. This submittal is in response to the Advisory Action mailed March 2, 2011. Applicant expresses appreciation to the Examiner for the thorough comments in the Advisory Action as well as for the earlier interview. Applicant's reply remarks relative to the Examiner's comments in the Advisory Action are included herein. Because the earlier response to the Final Office Action was not entered, the content of that response is incorporated below. Note in addition that claim 112 is different from the claim not entered, in part in response to the Examiner's comment in the Advisory Action (page 2, continuation of 3).

The thorough comments in the Advisory Action make clear that the un-entered response was carefully reviewed by the Examiner and it is understood that the Examiner continues to understand that the reference EP 1,129,742 A2 to Berthon-Jones et al. ("Berthon-Jones") remains the focus of concern since it is the only reference cited in the Advisory Action.

Claims 112-134 are pending in the present application. Claims 113-120 stand rejected under 35 U.S.C. § 112, second paragraph for improper antecedent bases in claims 113 and 117. Claims 112-115, 121-122, 125, and 128-134 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Berthon-Jones. Claims 116 and 123-124 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Berthon-Jones in view of the article entitled "An Adaptive Lung Ventilation Controller" (of record) by Laubscher et al. ("Laubscher"). Claims 118-120 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Berthon-Jones in view of Laubscher and in further view of WO 01/19440 A1 to Berthon-Jones ("Berthon-Jones '40"). Claims 126 and 127

stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Berthon-Jones and Berthon-Jones '40. In summary, all claims stand rejected at least in part on Berthon-Jones. As detailed below, Berthon-Jones does not disclose or suggest much of claim 112, such as but not limited to the two calculated errors and how the control responses are combined.

In response to the 35 U.S.C. § 112 rejection and the corresponding responses to arguments (Office Action, pg. 8), claims 113 and claim 117 are being amended.

The 35 U.S.C. § 102(b) rejection is the same as the one in the earlier non-final Office Action. Applicant timely responded to that Office Action and the Examiner's response to Applicant's arguments is included at the end of the final Office Action, including two paragraphs on page 9 which are separately addressed below:

Multiple Error Values

With regard to the "Responses to Arguments" section, page 9, first paragraph, the Final Office Action states that Berthon-Jones discloses the formula ($0.5 \mid f \mid - V_{TGT}$) for calculating multiple error values. This formula and discussion of it are the sole support in the Final Office Action for the contention that Berthon-Jones anticipates several limitations of the claims and no new support is introduced in the Advisory Action. However, the claims are directed to a different calculation completely and the calculation does not anticipate the claims for the reasons described below. This same point arises in the Advisory Action (pg. 2, continuation of 11, second and third full paragraphs).

As amended, the claims are directed to "a control mechanism for deriving two separate calculated errors, a fast-error and a slow-error, each of which is a function of

... a respective one of two different patient ventilation measures ..." (quoting claim 112, the only independent claim presently pending). That is, the claim is directed in part to deriving two separate calculated errors ("limitation 1") based on two different patient ventilation measures ("limitation 2"), and each error is a function of a different measure ("limitation 3"). Further, as described in at least one embodiment in the specification of the present invention, the different measures are different in that they are taken over different time intervals. ("limitation 4"). None of these four limitations is detailed in the portion of Berthon-Jones cited by the Examiner and none is anticipated by Berthon-Jones at all.

Measures are taken over different time intervals

The Advisory Action (pg. 2, continuation of 11, first full paragraph) references the previous paragraph, stating that "two different ventilation measures taken over different periods of time is not found in the present disclosure". The Examiner is directed to:

> One way of using a well-filtered ventilation measure for much of the time but being able to respond to severe hypoventilation quickly is to use two measures of ventilation with different speeds of response. The more rapidly responding measure of ventilation ("fast ventilation"), which fluctuates somewhat during a breath, has no effect on pressure support unless it is moderately below target, from which point as fast ventilation decreases further the more slowly responding measure ("slow ventilation") becomes progressively less important and fast ventilation becomes progressively more important in the calculation of pressure support, until a point is reached below which fast ventilation is the only determiner of pressure support.

(pg. 16, ln. 10-18, emphasis added). The two measures are mentioned and the mention of "different speeds of response" in the disclosure is the textual source for the measurements being taken over different time intervals.

Also, when read in context, the uses of the word "measure" in Berthon-Jones and in the present invention are completely different and, therefore, the use of the word "measure" in the present claims clearly is not anticipated by Berthon-Jones. As used in the present invention, a "measure" is a parameter associated with patient ventilation that requires a period of time (the word "measure" is used within "patient ventilation measure having a ... speed of response"). The "speed of response" terminology is indicative of a period of time of measurement. Logically, a fast speed of response is taken over a short time frame, whereas a slow speed of response is taken over a long time frame. Also, when shown in equation form, the ventilation is described as a function of time. See, for example, pg. 15, ln. 5, in which the actual ventilation is used in the equation $E(t) = V_{target} - V_{actual}(t)$.

The "measure", $V_{actual}(t)$, as the term is used in the specification, is ventilation at a specific time. In the claims, there are two such measures, each evaluated as an average over a different time interval from the other – one with a relatively fast speed of response evaluated over a short interval, and one with a relatively slow speed of response evaluated over a longer interval. These two "measures" capture a ventilation parameter over different length time periods of patient breathing, and are referred to in the specification as "fast ventilation" and "slow ventilation". The specification details multiple reasonings behind this approach, such as to be used in the algorithm for delivering ventilation while avoiding overcompensation. Also, neither of the measures in the present invention is of instantaneous flow, which is the measure used in Berthon-Jones. Claim 112 is being amended in part to make this distinction even clearer.

Again, the "measure" disclosed in Berthon-Jones is instantaneous flow, not flow averaged over an interval of time. Berthon-Jones is directed to a method to improve ventilatory flow to a patient. In Berthon-Jones, a ventilation template is applied in concert with a patient's respiratory cycle (see FIG. 1), with the template being comprised of a series of ventilation pressures to correspond to the various portions of a patient's respiratory cycle. In order to improve patient comfort, Berthon-Jones adjusts the template by applying a smoothing factor, K, where K is determined from measuring instantaneous respiratory airflow and determining deviation from a target. An adjusted template (such as shown in FIG. 3) is applied, and the process may iterate. Berthon-Jones includes a variable, f, which is the *instantaneous* ventilation. (see pg. 6, ln. 45, where the term is defined, emphasis retained). f is also alternatively defined as respiratory airflow (see pg. 2, ln. 24). Instantaneous ventilation, or instantaneous respiratory airflow, is the measure identified by the Examiner and is airflow at a moment in time, and not averaged over a period of time. Although a measure of f may be taken at more than one time, there still is only one way to take the "measure" in Berthon-Jones and this "measure" is f. The Examiner further relies on paragraph [0034] for disclosing two ventilation measures ("a measured value of f that is grossly under target as first ventilation measure which causes a fast speed of response and a measured value of f that is over or slightly below target as second ventilation measure which causes a slow speed of response", Advisory Action, continuation of 11, second complete paragraph). However, paragraph [0034] does not support Examiner's conclusion of disclosing two different ventilation measures. Paragraph [0034] is directed to explaining how the value of K changes based on a single measure of

instantaneous airflow. Paragraph [0034] makes no mention of a first or second anything. Even the example in paragraph [0034] is directed to a single instantaneous respiratory airflow of zero and how that impacts K. The Examiner states that support for multiple measures rests in f being a variable, but f being a variable does not infer or even suggest that multiple values of f are calculated or used, and a detailed reading of Berthon-Jones makes clear that multiple values of f are not used. As a result, limitation 4 is not anticipated by Berthon-Jones.

The calculation cited in the Office Action has two variables; f, which is a measure of flow (see paragraph 0019), and V_{TGT}, which is not a measure at all (and is not a measured quantity) but rather is a target ventilation (see paragraph 0036). The cited passage includes discussion of only one value for f, not two measures (1) as indicated in the Office Action or (2) as required by limitations 2 and 4 of the claims. Further, in the Advisory Action it is suggested that the two measures are two measures of f ("f is a variable and thus suggesting two measures of f", Advisory Action, pg 2, continuation of 11, second full paragraph). However, Berthon-Jones describes f as merely a single measure (see above). If there is only one measure, there cannot be two different errors where each is a function of a different measure, in contrast with limitation 3. Therefore, none of limitations 2-4 are anticipated by Berthon-Jones.

The Examiner also states that "[t]he error values can have a positive or negative sign and that the amplitude of the error values depends on the value of the airflow and how far it is away from a target V_{TGT}" (citing to paragraphs 0031, 0032). First, paragraphs 0031 and 0032 merely relate to the algorithm for selecting a value for K. Nothing in the cited sections explicitly references any error calculation. Second, the

relevance of the discussion of positive or negative error values is unclear. If the error value is ($0.5 \mid f \mid - V_{TGT}$), the reference is to a single measure, not different measures and whether the measured flow when mathematically adjusted is greater or less than the target. There is only one measure and only one error value in Berthon-Jones. Therefore, limitation 1 also is not anticipated by Berthon-Jones.

In addition, the Examiner indicates that the "error values can have a positive or negative sign" and appears to equate this difference in sign to "multiple error values" which are used to control the ventilator. However, the parameter is of a single value regardless of sign. Secondly, even if a positive f and a negative f are different measures, and they are not, the formula "ignores" this difference by taking the absolute value of f, thereby resulting in one "error" calculation and not two (in contrast with limitation 1). Therefore, for this additional reason, limitation 1 is not anticipated by Berthon-Jones.

The Advisory Action also includes a reference to the previous paragraph (Advisory Action, continuation of 11, third full paragraph) in which the Examiner suggests that the equation on page 6 can be applied multiple times, effectively suggesting that a first application can result in a first error being negative and a second application can result in a second error being positive. However, the calculation totally depends on f which, as previously discussed, is a single measure and for any value of f, Berthon-Jones only calculates one error, not two.

Two Different Measures

Further, another limitation of the claims previously discussed is the need for two particular measures – a relatively short measure and a relatively long measure

("limitation 5"). Even assuming the positive f and negative f are different measures, and they are not, there is nothing in the Berthon-Jones specification to suggest anything associated with two separate types of measures, one being relatively short and another being relatively long. That is, the Berthon-Jones positive and negative aspects of f reflect flow direction, not measure duration. Again, f is the only measure in Berthon-Jones and therefore, limitation 5 is not anticipated by Berthon-Jones.

In sum, Applicant respectfully disagrees with the remarks on page 9, first paragraph, and, as described above, re-affirms that claim 112 (the only independent claim) is not disclosed by Berthon-Jones in part precisely because the plain reading of Berthon-Jones does not disclose two different types of measures nor does it disclose any of the other three limitations detailed above.

With regard to the "Responses to Arguments" section, page 9, second paragraph, the Examiner states, with only a single ground of support, that Berthon-Jones discloses two control responses with the first based on $\Pi(\Phi)$ becoming a square wave when K=0 and the second based on $\Pi(\Phi)$ becoming a smooth wave when K=1. First, the applicable terminology in claim 112 is "said control mechanism further deriving two control responses of pressure to respective ones of said two calculated fast-error and slow-error errors ...". ("limitation 6"). The issue of Berthon-Jones not calculating two errors (the "limitation 1" discussion) was addressed above.

As a start, the "two" responses identified by the Examiner are actually the same response, $\Pi(\Phi)$. There is no reference to any second response. The Examiner also appears to be citing to paragraph 0029 and FIGs. 3 and 4 of Berthon-Jones in isolation and it is necessary to read them in the context of important accompanying text. First, in

terms of definitions, $\Pi(\Phi)$ is defined as a waveform template function (see paragraph 0005) and Φ is defined as the phase of the patient's respiratory cycle (see paragraph 0019). That is, $\Pi(\Phi)$ is a function of the patient's respiratory cycle, which itself changes during each cycle and from cycle-to-cycle. There is no "error" associated with any respiratory phase change and the change in patient effort results in an adjustment to the waveform template function $\Pi(\Phi)$, which is the response.

The Advisory Action (pg. 2, continuation of 11, final paragraph) makes reference to the previous paragraph, suggesting that $\Pi(\Phi)$ provides for two different control responses. Applicant disagrees and notes that $\Pi(\Phi)$ is a single response and no matter whether the response is to increase or decrease smoothness of a wave, it is still a single response. As described by the Examiner, the response is either to increase or decrease smoothness and not to combine them in any way. But, even more significantly, the claims of the present invention require that the control mechanism combine the two responses into a single response and the claims describe how they should be combined. Nothing like this claim requirement is even suggested by Berthon-Jones.

Also, the Office Action refers to K. K is a smoothing factor. K is determined based upon patient effort and the calculation of a new template $\Pi(\Phi)$ is based on K. Therefore, the waveform template is adjusted based upon patient effort and the template (which is a template for ventilation pressure as a function of respiratory phase), includes pressure changes corresponding to the applicable phase. These pressure changes are evident in FIGs. 3 and 4 (cited by the Examiner), and are explained throughout the disclosure, such as in paragraph 0021. Paragraph 0025,

which precedes the passages cited in the Office Action, provides initial context to the calculation for $\Pi(\Phi)$. "As the patient's ventilatory requirements increase, the smooth and comfortable waveform template changes to a progressively more square (and therefore more efficient, but generally less comfortable) waveform. In a preferred form, the pressure waveform template is a function of a smoothness variable K". That is, $\Pi(\Phi)$ is a function of K. Paragraph 0029 describes a calculation used relative to FIG. 4 and it is merely as an example (see paragraph 0026, which reads "FIG. 3 shows one way..." and paragraph 0029 which reads "FIG. 4 shows another method..."). Whether the equation of paragraph 0029 is used or another equation is used, there is only one control response implemented, $\Pi(\Phi)$, and based on the description, multiple concurrent control responses would not be meaningful and are not described. When read in context, paragraph 0029 and FIGs. 3 and 4 (cited in the Office Action) describe a single control response in Berthon-Jones manifested as a change in $\Pi(\Phi)$, no second control response, and the sole control response is a function of the variable K. Further, it is not the case that K is either 0 or 1; K is a variable that can range from 0 to 1 (per an example described in the Office Action), but the response still is a single response. Therefore, because the claim requires two different control responses and the only response in Berthon-Jones is a response of $\Pi(\Phi)$ to K, which is a single response and does not combine two response. Berthon-Jones does not anticipate the claim.

Based on the same portion of the Office Action, the Examiner appears to alternatively rely on the shape of the template as being indicative of different control responses because the Office Action specifically states "the first control response is when $\Pi(\Phi)$ becomes a square wave ... and the second control response is when $\Pi(\Phi)$

becomes a smooth wave ...". However, the very next sentence of the Office Action cites to paragraph 0042 and suggests the exact opposite – a gradual movement between the two extremes based on the value of K (meaning that as K changes, $\Pi(\Phi)$ changes). That is, for any value of K there is a single response under a single control. Even the cited paragraph does not suggest any more than one controlled response. Therefore, limitation 6 is not anticipated by Berthon-Jones.

In sum, Applicant respectfully disagrees with the Examiner relative to the remarks on page 9, second paragraph, and, as described above, re-affirms that claim 112 (the only independent claim) is not disclosed by Berthon-Jones in part precisely because the plain reading of Berthon-Jones includes only one and not two controlled responses. Further, Applicant has laid out a total of six limitations found in claim 112 which are not disclosed or suggested by Berthon-Jones.

Finally, with regard to the 35 U.S.C. § 102(b) rejection based solely upon Berthon-Jones, Applicant has identified five different limitations in the sole independent claim which are not disclosed by Berthon-Jones. Applicant respectfully requests reconsideration based upon the arguments presented above.

With regard to the various rejections under 35 U.S.C. § 103, all of these rejections are to dependent claims. Because of the arguments above, it is believed that independent claim 112 is in condition for allowance. Therefore, because independent claim 112 is in condition for allowance, the remaining dependent claims are also in condition for allowance. Also, as discussed above, at least six limitations of independent claim 112 are not disclosed by Berthon-Jones. None of these six limitations is disclosed or suggested by any of the secondary references either. Further

none of the references has any suggestion to combine with any other of the references cited. As a result, it is believed that claims 112 and 114-134 are in a condition for allowance, and the early passage to issue of the application is respectfully requested.

If any additional fee is required, the Commissioner is hereby authorized to charge the amount of any such fee to Deposit Account No. 07-1730, Docket No. 3869-029 US.

Respectfully submitted,
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